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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,011	03/05/2002	Gary L. Shuck	100/12710	7584

21569 7590 11/29/2005

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EXAMINER	
NAGPAUL, JYOTI	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,011	SHUCK, GARY L.	
	Examiner	Art Unit	
	Jyoti Nagpaul	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on September 1, 2005 has been acknowledged. Claims 1 and 4-30 are pending.

Response to Amendment

Rejection of **Claims 1-3, and 9-24** as being anticipated by Laugharn have been *withdrawn* in light of applicant's arguments.

Rejection of **Claims 4-8 and 25-30** as being unpatentable over Laugharn have been *withdrawn* in light of applicant's arguments.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1,9-14,18-20 and 23-28** are rejected under 35 U.S.C. 102(b) as being anticipated by Hasskamp (US 4537231).

Hasskamp teaches a fluid dispensing apparatus. The method of filling at least one microfluidic element of a microfluidic device with a gas or fluid comprises of placing the microfluidic device (32) in a vacuum chamber, applying a vacuum to the vacuum chamber and while the microfluidic device (32) remains under vacuum, introducing the gas or fluid. The method further comprises of venting the at least one microfluidic element (40) with the gas or fluid. The method further comprises of filling the at least one microfluidic device element (40) with the gas or fluid. The plurality of microfluidic

elements (40) comprise- a plurality of microfluidic channels (44). The plurality of microfluidic channels (44) is fluidly coupled to one or more micro-reservoirs (50). (See Figure 4) Hasskamp teaches, "Operation of the vacuum means then moves diaphragm portions 48 to their second positions causing an equal, predetermined amount of liquid to be drawn into each lower chamber 44. The application of vacuum is maintained while the pan is replaced with the tray, and operation of the valve means to connect port 78 to the atmosphere then causes diaphragm portions 48 to return to their first positions dispensing an equal amount of liquid to each well 36 in tray 38." (See Col. 4, Lines 38-47) Hasskamp further teaches filling the at least one microfluidic element (40) with at least one fluid selected from a group consisting of water, buffer, EDTA solution, DMSO, PEG, polyacrylamide, and NaOH solution. With respect to Claim 18, Hasskamp further teaches preparing at least one microfluidic device (44) for a gas or fluid-filling operation comprising placing the at least one microfluidic device (44) in a vacuum chamber (52) and applying a vacuum (79) to the vacuum chamber (52). Hasskamp teaches, "The manifold 74 is closed by a plate 76 which has an exit port 78 that receives a line 79 leading to a source of vacuum. When connected to such a vacuum source, the manifold becomes a main vacuum chamber 80 communicating with each concavity 54 by means of one or more of passageways 82 intersecting each concavity inner surface 64." (See Col. 4, Lines 14-20) (See Figure 4) Hasskamp further teaches placing two or more microfluidic channels (44) in the vacuum chamber (52). (See Figure 4) The method further comprises introducing at least one of gas or a fluid into the vacuum chamber (52) while the at least one microfluidic device (44) remains under vacuum.

Hasskamp teaches, "Operation of the vacuum means then moves diaphragm portions 48 to their second positions causing an equal, predetermined amount of liquid to be drawn into each lower chamber 44. The application of vacuum is maintained while the pan is replaced with the tray, and operation of the valve means to connect port 78 to the atmosphere then causes diaphragm portions 48 to return to their first positions dispensing an equal amount of liquid to each well 36 in tray 38." (See Col. 4, Lines 38-47) With respect to claim 23, Hasskamp teaches a chamber (52) configured to receive the microfluidic device (40), a vacuum source (79) which is fluidly coupled to the chamber (52) and which is configured to apply a vacuum to the chamber (52) and at least one source of a gas or fluid (40) which is fluidly coupled to the chamber (52) and which is configured to introduce at least one of gas or a fluid into the chamber (52). (See Figure 4) The microfluidic device comprises at least one micrfluidic channel (44).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 4-8 and 25-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasskamp.

Refer above for the teachings of Hasskamp.

Hasskamp fails to explicitly disclose applying a vacuum at the various ranges to the chamber.

The device of Hasskamp is clearly capable of adjusting to any desired pressure. It would have been obvious to one of the ordinary skill in the art to modify Hasskamp to include the various pressure ranges in order to minimize bubble formation of the microfluidic device.

6. **Claims 15-17,21-22 and 29-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasskamp in view of Swedberg (US 5571410).

Refer above for the teachings of Hasskamp.

Hasskamp fails to explicitly disclose filling the at least one microfluidic element with at least one inert gas and a processor operably coupled to the microfluidic device, wherein the processor comprises an instruction set for acquiring data from the detector and for controlling filling of the microfluidic device with the gas or fluid.

Swedberg teaches a liquid handling device. Swedberg teaches an external reservoir of gas or liquid (not shown) and a means whereby a pulse of gas or liquid may be expelled from the external reservoir. (See [127]) Swedberg further teaches a process or operably coupled to the microfluidic device wherein the processor comprises

an instruction set for acquiring data from the detector and for controlling filling of the microfluidic device with the gas or fluid. Swedberg teaches, "First detection means 234 can be used to monitor the presence of a sample in sample flow component 204 which is to be loaded onto second sample treatment component 216 or to monitor sample elution from first sample treatment component 214. In the latter case, it is preferred that first detection means 234 is placed in second sample flow component 204 upstream from second access port 224." (See [110])

It would have been obvious to one of the ordinary skill in the art to modify Hasskamp such that an inert gas is used to fill the microfluidic element and a processor is operably coupled to the microfluidic device in order to further expand the application of the device such that it can be used for assays requiring gasses and also increase monitoring of the desired dispensing volume.

Response to Arguments

Applicant's arguments with respect to claims 1 and 4-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JN

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